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| JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017 | | | EXAMINER DEJONG, ERIC S | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/015,167

Applicant(s)

USUKA ET AL.

Examiner

Eric S. DeJong

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15, 17, 20-22, 39, 40, 42, 45-47 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 17, 20-22, 39, 40, 42, 45-47 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 10/09/2007 has been entered.

Claims 1-13, 16, 18, 19, 23-38, 41, 43, 44, 48-57, and 59-77 are canceled.
Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are pending and are currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 14, 17, 20, 22, 39, 42, 45-47, and 58 each been amended to recite the limitation "identifying one or more genotypic data structures... that have correlation values that are higher than the correlation values for all other genotypic data structures" (see for example, lines 14-18 of claim 14). The instant specification fails to provide adequate support for the full scope of the newly recited limitation. The instant specification does disclose embodiments wherein statistical methods are used to identify highly correlated genotypic data structures by computation of a mean correlation value and selecting genotypic data structures that are several standard deviations above a calculated mean correlation value (see the instant specification at page 6, lines 15-25, page 28, line 3 through page 29, line 19, and page 31, lines 22-34). Further, the instant specification does disclose embodiments wherein specific correlation threshold values are used in order to identify those genotypic data structures that are considered the highest correlation values (see the instant specification at page 31, lines 15-21, page 32, lines 9-15, page 34, lines 16-29, page 35, line 25 through page 36, line 4, and the newly presented amendments to the specification following page 44, line 22, filed 10/09/2007). However, the instant specification does not provide support for the full scope of the broader limitation "identifying one or more genotypic data structures... that have correlation values that are higher than the correlation values for all other genotypic data structures" as instantly recited. Therefore, the amendment to the instant claims as

set forth above presents new matter. Claims 15, 21, and 40 are also included under this rejection due to their dependence from claims 14, 20, and 39, respectively.

Response to Arguments

Applicant's arguments filed 10/09/2007 have been fully considered but they are not persuasive.

In regards to the indication of new matter in the advisory action, mailed 08/21/2007, applicants argue that the instant specification provides ample teaching for the selection of the one or more genotypic data structures in the plurality of data structures that have correlation values that are higher than the correlation values for all other genotypic data structures in the plurality.

In response, it is reiterated that the instant disclosure does not provides support for the full scope of the instant claims. The specification provides does support for identifying highly correlated genotypic data structures by computation of a mean correlation value and selecting genotypic data structures that are several standard deviations above a calculated mean correlation value. Further, the instant specification does provide support for using specific correlation threshold values to identify those genotypic data structures that are considered the highest correlation values. However, the instant specification does not provide support for the full scope of the broader limitation "identifying one ore more genotypic data structures... that have correlation values that are higher than the correlation values for all other genotypic data structures" as instantly recited. Therefore applicants argument is not persuasive.

Claim Rejections - 35 USC § 112, Second Paragraph

The previous rejection of claims 14, 17, 20, 22, 39, 42, 45-47, and 58 as being indefinite as set forth in the previous Office action, mailed 02/01/2007, is withdrawn in view of amendments made to the instant claims, filed 10/09/2007.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are drawn to methods, related computer system and program products for associating a phenotype with one or more candidate chromosomal region in a genome of a species and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999))). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are not limited to producing only a concrete and tangible result. It is acknowledged that the instant claims have been amended to recite "communicating one or more genotypic data structures to a user, a display, a readily accessible computer memory or other computer on a network" (see for example lines 41 and 42 of claim 14). It is further acknowledged that in the previous Office action, mailed 02/01/2007 indicated that an amendment to the instant claims so as to recite that a result is outputted to a user, a display, a readily accessible computer memory or other computer on a network would be sufficient to overcome the instant rejection. However, the recent decision issued by the Federal Circuit Court of Appeals in *In re Nuijten* ((2006-1371), decided on September 20, 2007)) set forth that signals, encompassing the transmission of information, are transitory in nature and do not encompass statutory subject matter. In the instant case, the recited step of "communicating" a result to "a readily accessible computer memory or other computer on a network" does not produce a concrete and tangible result as said embodiments read on the generation of a transitory signal and thus are not concrete and tangible.

For the benefit of applicants, an amendment to the instant claims so as to recite

--outputting one or more genotypic data structures to a user or a display-- would be sufficient to overcome the instant rejection. It is further noted that the output of a result to a readily accessible computer memory or other computer on a network would be considered as encompassing non-statutory embodiments.

Claims 39, 40, 42, and 45-47 are each drawn to a "computer program product comprising a computer readable storage medium and a computer program mechanism embedded therein" (see for example lines 2 and 3 of claim 39). The instant specification does not provide a limitation definition for the recited "computer readable storage medium" as encompassing only physical computer readable media. Further, the computer program mechanism as set forth in the instant claims comprises only data and executable program instructions and is not limited to requiring any physical component. Therefore, the instant claims read on embodiments wherein a computer program is disposed only a signal or electromagnetic carrier wave. As set forth in *In re Nuijten* (see above) signals, encompassing the transmission of information, are transitory in nature and do not encompass statutory subject matter. Therefore, the instant claims are not limited only to statutory embodiments.

For the benefit of applicants, an amendment to the instant claims so as to recite -- a *physical* computer readable storage medium -- (emphasis added) would be sufficient to overcome the instant rejection.

Response to Arguments

Applicant's arguments with respect to the rejection of claims under 35 USC § 101 have been considered but are moot in view of the new grounds of rejection set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Satagopan et al. (see List of References cited by examiner, mailed 10/19/2004).

Satagopan et al. describes a method for associating a phenotype with one or more candidate chromosomal positions using a multi-locus model (Abstract etc., and

page 806, lines 1-2). The method of Satagopan et al. is directed to using phenotypic data for *Brassica napus* (species) wherein "[a]t each marker locus and the putative QTL, associate 1 with one homozygous parent type, -1 with the other homozygous parent type and 0 with the heterozygote" (strains). The phenotypic (flowering time) and genotypic (genetic marker loci) data structures are defined by the linear model (structure) of equations 1-6 (establish) wherein Tables 1-3 are populated (database) with data from said model. The location of the putative locus, its phenotype and effects can be estimated from said model by assuming an appropriate distribution for the traits (variation) (pages 806-807, QTL Model §, and pages 810-811, The data and model structure). The models are being compared to a correlation value wherein the ratio of marginal probabilities of the two compared models is the Bayes factor (page 809, column 2, lines 29-47), as in instant claim 14, lines 8-9; claim 39, lines 16-17; and claim 46, lines 16-17. Satagopan et al. describes five repeated runs of the chain using normal and multivariate t weighting densities (identified correlations between genotypic data structure and phenotypic data structure, correlation values weighted by a number of components corresponding to the genotypic data structure) (see Figures 2 and 7). Satagopan et al. further disclose the estimate of the location of marker locations plotted against marginal posterior density (X in Figures 2 and 7), a threshold above which marginal posterior density for several marker loci meet a 90% HPD confidence level, which reads on the identification of genotypic data structures that have high correlation values higher than the correlation value for all others (see also Figures 2 and 7).

While Satagopan et al. discloses the above described computational method for associating a phenotype with one or more candidate chromosomal positions using a multi-locus model, Satagopan et al. does not expressly teach A computer program product comprising a computer readable storage medium and computer mechanism embedded therein. However, Regarding computer-related inventions, the MPEP §2106 (VI) states:

"Reviewing a claimed invention for compliance with 35 U.S.C. 102 and 103 begins with a comparison of the claimed subject matter to what is known in the prior art. See MPEP §2131 - § 2146 for specific guidance on patentability determinations under 35 U.S.C. § 102 and 103. If no differences are found between the claimed invention and the prior art, then the claimed invention lacks novelty and is to be rejected by USPTO personnel under 35 U.S.C. 102. Once differences are identified between the claimed invention and the prior art, those differences must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies 35 U.S.C. 103."

Factors and considerations dictated by law governing 35 U.S.C. 103 apply without modification to computer-related inventions. Moreover, merely using a computer to automate a known process does not by itself impart nonobviousness to the invention. See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958). See also *Dann v. Johnston*, 425 U.S. 219, 227-30, 189 USPQ 257, 261 (1976).

Therefore it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to rely on a computer program and system to automate the computational method for associating a phenotype with one or more candidate chromosomal positions using a multi-locus model, as taught Satagopan et al., because using a computer to automate a known process does not by itself impart nonobviousness. Further, one of ordinary skill in the art would have a reasonable expectation of success because the disclosed method of

Satagopan et al. requires complex algorithmic procedures and data processing that is typically carried out by computer implementation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Moran Marjorie can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric S DeJong
Examiner
Art Unit 1631


01/05/2008